IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

SULLIVAN et al.

Appln. No.:
Div of Appln. No. 08/934,176 Group Art Unit: 3737

Filed: January 18, 2002 Examiner: CASLER, B.

Title: METHOD AND APPARATUS USEFUL IN THE DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA OF A PATIENT (As Amended)

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January 18, 2002

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents
Washington, D.C. 20231

Sir:

Before examination on the merits, please amend this application as follows:

IN THE TITLE:

Please amend the Title to read as follows:

--METHOD AND APPARATUS USEFUL IN THE DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA OF A PATIENT--

IN THE SPECIFICATION:

At page 1, line 5, please insert the following new paragraph as follows:

--CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional application of U.S. Application No. 08/934,176, filed September 19, 1997, currently pending, which is a continuation of U.S. Application No. 08/838,462, filed April 7, 1997, now abandoned, which is a continuation of U.S. Application No. 08/654,742, filed May 29, 1996, now abandoned, which is a continuation of U.S.

Application No. 08/385,742, filed February 8, 1995, now abandoned, which is a divisional of U.S. Application No. 08/100,556, filed July 30, 1993, now abandoned, which is a divisional of U.S. Application No. 07/892,692, filed May 27, 1992, now U.S. Patent No. 5,245,995, which is a continuation of U.S. Application No. 07/548,108, filed July 5, 1990, now abandoned, which is a continuation-in-part of U.S. Application No. 07/457,757, filed December 21, 1989, now abandoned, the specifications and drawings of which are incorporated herein by reference.--

At page 1, after "BACKGROUND ART," lines 6-8, please delete the entire first paragraph.

See the attached Appendix for the changes made to effect the above paragraph

IN THE CLAIMS:

Please cancel claim 1 without prejudice.

Please enter the following new claims 25-71.

25. (New) An apparatus useful in the diagnosis of obstructive sleep apnea of a patient, the apparatus comprising:

a pressure sensor in communication with a nasal mask, the pressure sensor being configured to provide a recordable signal indicative of the patient's snoring and flow rate.

26. (New) An apparatus according to claim 25, further comprising a processor associated with the pressure sensor and configured to process the recordable signal.

27. (New) An apparatus according to claim 25, further comprising a data recording apparatus associated with the pressure sensor, the data recording apparatus configured to record and store the recordable signal over a period of time.

28. (New) An apparatus according to claim 25, further comprising a feedback system configured to monitor the patient's snoring and flow rate, wherein the patient's snoring and flow rate are compared with predetermined snoring and flow rate patterns so as to control pressure within the nasal mask.

29. (New) An apparatus according to claim 25, wherein the pressure sensor connects to the nasal mask adjacent an air inlet of the nasal mask to provide the recordable signal.

30. (New) An apparatus according to claim 25, wherein the apparatus is configured to monitor breathing of the patient while sleeping substantially unsupervised in a non-clinical setting.

31. (New) An apparatus according to claim 25, wherein the pressure sensor is connected remote from the nasal mask so as to be in pressure communication with the patient's respiratory system to provide the signal.

32. (New) An apparatus according to claim 25, wherein the pressure sensor is a pressure transducer.

33. (New) An apparatus according to claim 25, wherein the recordable signal provides at least one index useful in the diagnosis of obstructive sleep apnea.

34. (New) An apparatus according to claim 31, wherein the at least one index provides a sleep disorder clinical professional information without the requirement for clinical sleep supervision.

35. (New) An apparatus according to claim 32, wherein the index is utilized as a screening device configured to screen the patient for an indication of obstructive sleep apnea.

36. (New) An apparatus according to claim 25, further comprising:

a parameter monitor configured to monitor a non-respiratory parameter,

wherein the apparatus provides data indicative of the diagnosis of obstructive sleep apnea of a patient based on at least one of the monitored snoring and flow rate and the non-respiratory parameter.

37. (New) An apparatus as in claim 36, wherein the non-respiratory parameter includes one of pulse oximetry and ECG.

38. (New) An apparatus as in claim 36, wherein the non-respiratory parameter is a non-EKG parameter.

39. (New) A method useful in the diagnosis of obstructive sleep apnea of a patient, the method comprising:

providing a signal indicative of the patient's snoring and flow rate;

sensing the patient's snoring and flow rate; and

recording and storing the signal over a period of time.

40. (New) A method according to claim 39, further comprising processing the signal to diagnose obstructive sleep apnea of the patient.

41. (New) A method according to claim 39, further comprising:

providing a predetermined snoring and flow rate pattern;

comparing the patient's snoring and flow rate with the predetermined snoring and flow rate pattern; and

controlling pressure within the nasal mask based on the comparison between the patient's snoring and flow rate and the predetermined snoring and flow rate pattern.

42. (New) A method according to claim 39, further comprising connecting a pressure sensor to the nasal mask adjacent an air inlet of the nasal mask to provide the signal.

43. (New) A method according to claim 39, wherein the sensing of the patient's snoring and flow rate is performed while the patient is sleeping substantially unsupervised in a non-clinical setting.

44. (New) A method according to claim 39, further comprising connecting a pressure sensor remote from the nasal mask so as to be in pressure communication with the patient's respiratory system to provide the signal.

45. (New) A method according to claim 39, further comprising providing the signal to a sleep disorder clinical professional in the diagnosis of obstructive sleep apnea.

46. (New) A method according to claim 39, further comprising processing the signal to provide at least one index useful in the diagnosis of obstructive sleep apnea.

47. (New) A method according to claim 46, further comprising reviewing the index to screen the patient for an indication of obstructive sleep apnea.

48. (New) A method according to claim 39, monitoring a non-respiratory parameter.

49. (New) A method according to claim 48, wherein the non-respiratory parameter includes one of pulse oximetry and ECG.

50. (New) A method according to claim 48, wherein the non-respiratory parameter is a non-EKG parameter.

51. (New) An apparatus for diagnosing obstructive sleep apnea of a patient, the apparatus comprising:

a pressure monitor configured to monitor at least one respiratory parameter of the patient, the pressure monitor including a pressure sensor connected to a nasal mask adjacent an air inlet of the nasal mask to provide a recordable signal indicative of the at least one respiratory parameter.

52. (New) An apparatus according to claim 51, further comprising a processor associated with the pressure monitor and configured to process the recordable signal.

53. (New) An apparatus according to claim 51, wherein the pressure sensor connects to the nasal mask in sound communication.

54. (New) An apparatus according to claim 51, further comprising a data recording apparatus associated with the pressure sensor, the data recording apparatus being configured to record and store the recordable signal over a period of time.

55. (New) An apparatus according to claim 51, further comprising a feedback system configured to monitor the at least one respiratory parameter of the patient, wherein at least one of the patient's snoring and flow rate are compared with at least one of a predetermined snoring pattern and a predetermined flow rate pattern so as to control pressure within the nasal mask.

56. (New) An apparatus according to claim 51, wherein the at least one respiratory parameter includes the patient's snoring and flow rate.

57. (New) An apparatus according to claim 51, wherein the apparatus is configured to monitor the at least one respiratory parameter while the patient is sleeping substantially unsupervised in a non-clinical setting.

58. (New) An apparatus according to claim 51, wherein the pressure sensor is connected remote from the nasal mask so as to be in pressure communication with the patient's respiratory system to provide the recordable signal.

59. (New) An apparatus according to claim 51, wherein the pressure sensor is a pressure transducer.

60. (New) An apparatus according to claim 51, wherein the recordable signal provides at least one index useful in the diagnosis of obstructive sleep apnea

61. (New) An apparatus according to claim 60, wherein the at least one index provides a sleep disorder clinical professional information without the requirement for clinical sleep supervision.

62. (New) An apparatus according to claim 60, wherein the index is utilized to screen the patient for an indication of obstructive sleep apnea.

63. (New) An apparatus according to claim 51, further comprising:

a parameter monitor configured to monitor a non-respiratory parameter,

wherein the apparatus provides data indicative of the diagnosis of obstructive sleep apnea of the patient based on at least one of the monitored at least one respiratory parameter and the non-respiratory parameter.

64. (New) An apparatus as in claim 63, wherein the non-respiratory parameter includes one of pulse oximetry and ECG.

65. (New) An apparatus as in claim 63, wherein the non-respiratory parameter is a non-EKG parameter.

66. (New) A method of diagnosing and treating sleep apnea, comprising:

providing a patient with a home use snoring monitoring;

monitoring the patient during sleep at said patient's home and generating data indicative thereof;

diagnosing the presence of sleep apnea in accordance with said data; and for said patient producing snoring data which indicate the presence of sleep apnea, treating sleep apnea by:

providing the patient with a feedback controlled CPAP device,

monitoring snoring patterns of said patient during sleep;

raising CPAP pressure upon detection of predefined snoring patterns;

decreasing CPAP pressure in the absence of the predefined snoring patterns.

67. (New) A method for determining the appropriate CPAP setting for a patient suspected of suffering from sleep apnea, comprising:

providing said patient with a home use breathing pattern monitor;

monitoring at least one breathing parameter of the patient during sleep at said patient's home;

generating data indicative of one or more breathing parameters measured during said patient's sleep at home;

analyzing said data for the presence of sleep apnea;

for said patient demonstrating breathing parameters indicative of the presence of sleep apnea, referring said patient to a clinical environment for at least one night of further monitoring; and

determining the appropriate CPAP setting for said patient's condition.

68. (New) A method of diagnosing the presence of sleep apnea in a patient, comprising:

generating data indicative of the frequency and intensity of a patient's snoring patterns during the patient's sleep at home using a microphone, which is not in direct contact with any part of the patient's body; and

analyzing said data to discern patterns of snoring monitored during said patient's sleep at home for the presence of sleep apnea; and

diagnosing the presence of sleep apnea based on said analysis of said data.

69. (New) A method of treating sleep disordered breathing at home without supervision, said method comprising:

setting a first air flow pressure;

providing a monitoring device for monitoring at least one respiratory parameter of said subject while sleeping substantially unsupervised in a non-clinical setting, said monitoring device being configured to generate a signal indicative of the parameter being monitored;

monitoring at least one respiratory parameter of said subject using said monitoring device;

processing said signal; and

adjusting said first air flow pressure, based on said signal, to provide a continuous minimum appropriate pressure for substantially the entire period of therapy.

70. (New) A method to permit a patient at home to reduce the necessary airway pressure by some amount while still preventing the occurrence of obstructive sleep apnea, said method comprising:

setting a first air flow pressure sufficient to prevent the occurrence of obstructive sleep apnea;

providing a monitoring device for monitoring at least one respiratory parameter of said subject while sleeping substantially unsupervised in a non-clinical setting, said monitoring device being configured to generate a signal indicative of the parameter being monitored;

monitoring at least one respiratory parameter of said subject using said monitoring device;

processing said signal; and

based on said signal, adjusting said first air flow pressure to provide a continuous minimum appropriate pressure for preventing the occurrence of obstructive sleep apnea.

71. (New) A method to select at home the lowest practicable airway pressure that is effective in preventing airway occlusions during CPAP therapy, said method comprising:

setting a first air flow pressure sufficient to prevent the occurrence of obstructive sleep apnea;

providing a monitoring device for monitoring at least one respiratory parameter of said subject while sleeping substantially unsupervised in a non-clinical setting, said monitoring device being configured only to generate a signal indicative of the parameter being monitored;

monitoring at least one respiratory parameter of said subject using said monitoring device;

processing said signal; and

based on said signal, adjusting said first air flow pressure to the lowest practicable airway pressure that is effective in preventing airway occlusions during CPAP therapy.

IN THE ABSTRACT OF THE DISCLOSURE:

Please add the Abstract of the Disclosure which is provided on the attached separate page.

REMARKS

Claim 1 is cancelled herein, new claims 25-71 are added.

Claims 25-50, 51-65 and 66-71 correspond to claims 146-171, 185-199 and 91-96 from the immediate parent application, respectively. Claims 91-96 were restricted in the parent application, thusly making a first office final rejection improper in this application.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached Appendix is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE"**.

Respectfully submitted,

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Attachment: Appendix

APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE:

Please amend the Title to read as follows:

--METHOD AND APPARATUS USEFUL IN THE DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA OF A PATIENT— **[DEVICE FOR MONITORING BREATHING DURING SLEEP AND CONTROL OF CPAP TREATMENT]**

IN THE SPECIFICATION:

At page 1, line 5, please insert the following new paragraph as follows:

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a divisional application of U.S. Application No. 08/934,176, filed September 19, 1997, currently pending, which is a continuation of U.S. Application No. 08/838,462, filed April 7, 1997, now abandoned, which is a continuation of U.S. Application No. 08/654,742, filed May 29, 1996, now abandoned, which is a continuation of U.S. Application No. 08/385,742, filed February 8, 1995, now abandoned, which is a divisional of U.S. Application No. 08/100,556, filed July 30, 1993, now abandoned, which is a divisional of U.S. Application No. 07/892,692, filed May 27, 1992, now U.S. Patent No. 5,245,995, which is a continuation of U.S. Application No. 07/548,108, filed July 5, 1990, now abandoned, which is a continuation-in-part of U.S. Application No. 07/457,757, filed December 21, 1989, now abandoned, the specifications and drawings of which are incorporated herein by reference.

At page 1, after "BACKGROUND ART," lines 6-8, please delete the entire first paragraph.

[This application is a continuation-in-part of Application Serial No. 07/457,757 filed December 21, 1989.]

IN THE CLAIMS:

Please cancel claim 1.

New claims 25-71 are added.

IN THE ABSTRACT:

An Abstract has been added.

ABSTRACT OF THE DISCLOSURE

Patients may operate a CPAP system to deliver appropriate airway pressure at their home. A patient's apnea problem ca be diagnosed at home without supervision with a CPAP device which delivers a continuously minimum appropriate pressure for substantially the entire period of therapy.